EXHIBIT A

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, *ex rel.*	)	
	)	Civil A. No. 18-1688-PD
[UNDER SEAL]	)	
v.	)	**FILED UNDER SEAL** **Pursuant to 31 U.S.C. §3730(b)(2)**
[UNDER SEAL]	)	
	)	JURY TRIAL DEMANDED

SECOND AMENDED COMPLAINT FOR DAMAGES AND OTHER RELIEF UNDER THE *QUI TAM* PROVISIONS OF THE FALSE CLAIMS ACT AND SIMILAR STATE PROVISIONS

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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

United States of America, and the States of Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Washington, Wisconsin and the District of Columbia, and the Cities of Chicago and New York Plaintiffs, *ex rel.* John Doe and Jack Doe, Relators, v. BioTelemetry, Inc. and CardioNet, LLC, Defendants.	**Civil Action No. 18-1688-PD** **FILED UNDER SEAL** **Pursuant to 31 U.S.C. §3730(b)(2)** **JURY TRIAL DEMANDED** **DO NOT POST ON PACER**

SECOND AMENDED COMPLAINT FOR DAMAGES AND OTHER RELIEF UNDER THE *QUI TAM* PROVISIONS OF THE FALSE CLAIMS ACT AND SIMILAR STATE PROVISIONS

1. This is an action, brought by Relators John Doe and Jack Doe (collectively, "Relators"), to recover damages and civil penalties on behalf of the United States of America, and numerous state and local governments arising out of false claims and records presented to the United States and to the States, the District of Columbia, and the Cities of Chicago and New York (the "*Qui Tam* States") by Defendants BioTelemetry, Inc. and CardioNet, LLC (collectively, "Defendants").

2. This action arises under the provisions of Title 31 U.S.C. §3729 *et seq*., popularly known as the False Claims Act (the "FCA"), and pursuant to analogous provisions of state and local law, including, but not limited to the following:

Arkansas Medicaid Fraud False Claims Act, Ark. Code Ann. § 20-77-901
California False Claims Act, Cal. Gov't Code § 12651 *et seq*.
California Insurance Frauds Prevention Act, California Insurance Code § 1871.7 *et seq*.
Colorado Medicaid Assistance Act, Rev. Stat. § 25.5-4-304 *et seq.*
Connecticut False Claims Act, Chapter 319v § 17b-301a *et seq.*
Delaware False Claims and Reporting Act, Del. Code Tit. 6, § 1201 *et seq.*
Florida False Claims Act, Fla. Stat. § 68-081 *et seq.*
Georgia False Medicaid Claims Act, Ga. Code § 49-4-168 (2007)
Hawaii False Claims Act Against the State, Haw. Rev. Stat. § 661-21 *et seq.*
Illinois False Claims Act and Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. 175/1 *et seq.*
Illinois Insurance Claims Frauds Prevention Act, 740 Ill. Comp. Stat. § 92
Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5 *et seq.*
Iowa False Claims Act, Iowa Code § 685.1 *et seq*.
Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. § 46:437.1 *et seq.*
Maryland False Claims Act, Md. Code Ann., Health-Gen. § 2-6-1 *et seq.*
Massachusetts False Claims Act, Mass Laws Ch. 12, § 5(A) *et seq.*
Michigan Medicaid False Claims Act, Mich. Comp Laws Serv. § 400.601 *et seq.*
Minnesota False Claims Act, Minn. Stat. § 15C.01 *et seq.*
Montana False Claims Act, Mont. Code § 17-8-401 *et seq.*
Nevada Submission of False Claims to State or Local Government Act, Nev. Rev. Stat. § 357.010 *et seq.*
New Jersey False Claims Act, N.J. Stat. § 2A:32C-1 *et seq.*
New Mexico Medicaid False Claims Act., N.M. Stat § 27-14-1 *et seq.*
New York False Claims Act, N.Y. St. Fin. Law § 187 *et seq.*
North Carolina False Claims Act, N.C. Gen. Stat. § 1-605 *et seq.*
Oklahoma Medicaid False Claims Act, 63 Okla. St. § 5053 *et seq.*
Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1 *et seq.*
Tennessee False Claims Act, Tenn. Code § 4-18-101 *et seq.*
Tennessee Medicaid False Claims Act, Tenn. Code § 71-5-181 *et seq.*
Texas Medicaid False Claims Act, Tex. Hum. Res. Code § 36.001 *et seq.*
Virginia Fraud Against Taxpayers Act, Va. Code § 8.01-216.1 *et seq.*
Washington Medicaid Fraud False Claims Act, RCW 74.66.020
Wisconsin False Claims Act, Wis. Stat. § 20.931 *et seq.*
District of Columbia False Claims Act, D.C. Code § 2-308.13 *et seq.*
City of Chicago False Claims Ordinance, Mun. Code, § 1-22-010 *et seq.*
City of New York City False Claims Act, Adm. Code § 7-801 *et seq.*

(collectively, "State False Claims Acts").

3. These false or fraudulent claims for reimbursements were submitted, or caused to be submitted, by Defendants to government-funded healthcare programs including, without limitation, Medicare, Medicaid, the Federal Employees Health Benefits Program, TRICARE/CHAMPUS, and the Veterans Administration[1] for the utilization of external, ambulatory telemetry cardiac monitoring devices and/or related services.

I. JURISDICTION AND VENUE

4. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732(a), which specifically confer jurisdiction to this Court over actions brought pursuant to 31 U.S.C. §§ 3729 and 3730.

5. This Court has supplemental subject matter jurisdiction over Defendants' violations and the counts relating to the State False Claims Acts pursuant to 28 U.S.C. § 3732(b) because Defendants' violations of the State False Claims Acts and/or the federal FCA arise out of a common nucleus of operative fact. *See also* 31 U.S.C. § 3732(b) (granting district court jurisdiction over any action brought under the laws of any state for the recovery of funds paid by a state if the action arises from the same transaction or occurrence as an action brought under the federal FCA).

6. This Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. § 3732(a) because acts prohibited by 31 U.S.C. § 3729 occurred in this state and this judicial district.

7. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b)-(c) because Defendants transact business within this District and because acts proscribed by 31 U.S.C. § 3729 occurred within this District.

[1] These government-funded healthcare programs are collectively referred to as "Government Healthcare Programs."

II. PARTIES

8. Relator John Doe is a citizen of the United States. He is familiar with the Defendants' business operations. Further details regarding Relator John Doe and his knowledge have been and will be provided to the United States and the *Qui Tam* States.

9. Relator Jack Doe is a citizen of the United States. He is familiar with the Defendants' business operations. Further details regarding Relator Jack Doe and his knowledge have been and will be provided to the United States and the *Qui Tam* States.

10. Defendant BioTelemetry, Inc. ("BioTelemetry"), formerly known as CardioNet, Inc., is a mobile and wireless medical technology company. BioTelemetry is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1000 Cedar Hollow Road, Malvern, Pennsylvania 19355.

11. Defendant CardioNet, LLC ("CardioNet") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1000 Cedar Hollow Road, Malvern, Pennsylvania 19355. CardioNet is a provider of ambulatory outpatient management solutions for monitoring clinical information regarding an individual's health.

12. CardioNet is a wholly-owned subsidiary of Defendant BioTelemetry.

13. In a recent Annual Report (10-K), BioTelemetry stated "[w]e market our services throughout the United States and receive reimbursement for the monitoring provided to patients from Medicare and other third-party commercial payors." BioTelemetry further specified that approximately 34% of the company's total revenue from 2017 derives from reimbursement from the Medicare program. No other payor accounted for more than 4% of the company's total revenue. Moreover, for the years ended December 31, 2016 and 2015, revenue from Medicare as a percentage of total revenue was 33% and 34%, respectively.

14. CardioNet's Mobile Cardiac Outpatient Telemetry™ (MCOT™) device was the first commercialized mobile cardiac telemetry ("MCT") device on the market.

15. CardioNet claims that its MCOT technology includes "beat-to-beat, real-time analysis automatic arrhythmia detection, and wireless ECG [electrocardiographic] transmission."

16. CardioNet received FDA 510(k) marketing approval for its MCOT system in February 2002.

17. CardioNet has been awarded a contract under the federal Supply Schedule program (V797P-4361B), which includes the 65II, A-51 and A-54 (Tele-Home Care, ECG/EKG Apparatus, and Holter Cardiograph Apparatus) schedule for CardioNet's MCOT™.

18. In March 2015, BioTelemetry agreed to pay $6.4 million to resolve allegations made under the FCA that CardioNet overbilled Medicare and other federal healthcare programs for its MCOT services when those services were not reasonable or medically unnecessary. *See* https://www.justice.gov/opa/pr/cardiac-monitoring-company-pay-64-million-alleged-overbilling-government-health-care-programs

19. The government investigation revealed that CardioNet, which did not provide 24/7 monitoring, was aware that MCT services were not eligible for Medicare reimbursement when provided to patients who had experienced only mild or moderate heart palpitations, since less expensive "Event" or "Holter monitors" could effectively collect data about those patients' conditions. Nonetheless, CardioNet knowingly submitted claims to Medicare for more expensive MCT services by using an inaccurate diagnostic code that ensured that the claims would be reimbursed by Medicare at a higher rate.

20. In its press release, the Department of Justice defined CardioNet's MCOT device as follows:

> An MCOT monitor provides real-time, outpatient cardiac monitoring. MCOT monitors are worn by patients for a period of time during which the device continuously records the activities of the patient's heart, including any irregular rhythms or other cardiac event, and transmits data to CardioNet's diagnostic center using cell phone technology. Traditional, less expensive event monitors only download patient data periodically over a landline.

21. In July 2017, BioTelemetry announced the acquisition of LifeWatch AG, which had its headquarters in Zug, Switzerland. LifeWatch AG is a healthcare technology and solutions company, specializing in advanced digital health systems and wireless remote diagnostic patient monitoring services. LifeWatch AG has operative subsidiaries in the United States, and is the parent company of LifeWatch Services Inc. ("LifeWatch"), a U.S.-based provider of cardiac monitoring services.

22. Like Cardio Net, LifeWatch provided, and continues to provide, services to Government Healthcare Programs. For example, LifeWatch operates as TRICARE in-network provider for telemetry services (Contract Number V797P-4167b). This contract is valid through December 31, 2018, and identifies LifeStar ACT Ambulatory Cardia Telemetry as the service.

23. In March 2012, LifeWatch agreed to pay the United States $18.5 million to resolve allegations that the company submitted false claims to federal healthcare programs relating to its ambulatory cardiac telemetry (ACT) services.

24. In addition to the monetary settlement, LifeWatch entered into a Corporate Integrity Agreement (CIA) with the Office of Inspector General of the U.S. Department of Health and Human Services to ensure its continued compliance with federal health care benefit program requirements.

25. At all times relevant to this Complaint, Defendants have manufactured and marketed various cardiac monitoring devices and provided and marketed technical services related to ambulatory cardiac monitoring devices capable of detecting abnormal cardiac rhythms.

26. At all relevant times, Defendants have also operated Independent Diagnostic Testing Facilities ("IDTF") staffed by technicians who monitor data reported by the device and provide physicians with reported results and analysis.

27. When a patient is using a cardiac device, IDTFs are supposed to monitor the patient's electrical heart activity, analyze the results, and provide interpretations and reports to the patient's treating physician.

III. PRELIMINARY STATEMENT

28. In accordance with 31 U.S.C. § 3730(b)(2), this Second Amended Complaint is being filed under Seal.

29. This suit is not based upon prior public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, lawsuit or investigation, in a Government Accountability Office or Auditor General's report, hearing, audit, or investigation, from the news media, or in any other location as the term "publicly disclosed" is defined in 31 U.S.C. § 3730 (e)(4)(A), amended by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1313(j)(2), 124 Stat. 901-902 (2010) ("PPACA"). Moreover, Relators affirmatively disclosed the allegations herein to the United States Attorneys' Office for the Eastern District of Pennsylvania prior to filing this action.

30. To the extent there has been a public disclosure of the information upon which the allegations of this Second Amended Complaint are based that is unknown to Relators, Relators are "original sources" of this information as defined in 31 U.S.C. § 3730(e)(4)(B), amended by the PPACA, *supra*, and similar state law provisions.

31. Relators possess direct and independent knowledge of the information in this Second Amended Complaint by virtue of their role as employees employed in this industry.

32. Relators' counsel voluntarily provided the United States with information related to this claim prior to filing this action. *See* 31 U.S.C. § 3730(e)(4).

IV. APPLICABLE FEDERAL LAW

A. Federally-Funded Healthcare Programs

33. The Medicare Program ("Medicare") is a health insurance program administered by the Government of the United States that is funded by taxpayer revenue. Medicare is directed by the U.S. Department of Health and Human Services ("HHS"). Medicare was designed to assist in providing medical services and durable medical equipment to persons over sixty-five (65) years of age and certain others who qualify for Medicare because of disability or end stage renal disease. Generally speaking, if one is eligible for Medicare, Part A covers hospital, inpatient, nursing home, and other institutional care; Part B covers doctor visits and outpatient services; and Part D provides prescription drug coverage.

34. The Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v (hereafter, "Medicaid"), is a health insurance program administered by the Government of the United States and the various individual States and is funded by state and federal taxpayer revenue. The Medicaid program is overseen by the HHS through its Centers for Medicare and Medicaid Services ("CMS").

35. Medicaid was designed to assist participating states in providing medical services, durable medical equipment and prescription drugs to, among others, financially needy individuals that qualify for Medicaid. The States directly pay providers, with the States obtaining the federal share of the payment from accounts which draw on the United States Treasury. 42 C.F.R. §§ 430.0-430.30 (1994).

36. Federal funding for the Medicaid program includes support for Medicare Savings Programs which help qualifying Medicare beneficiaries pay Part A and B premiums, copayments, co-insurance, and deductibles. The Medicare Savings Programs consist of the Qualified Medicare Beneficiary (QMB) Program, 42 U.S.C. §1396d(p)(1), the Specified Low Income Medicare Beneficiary (SLMB) Program, 42 U.S.C. § 1396a(a)(10)(E)(iii), the Qualifying Individual (QI) Program, 42 U.S.C. § 1396a(a)(10)(E)(iv), and the Qualified Disabled and Working Individuals (QDWI) Program, 42 U.S.C. § 1396d(s).

37. There are a number of other health insurance programs funded by the federal government. Among these are the following:

a. the Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS") (now known as "TRICARE"), 10 U.S.C. §§ 1071-1106, provides benefits for health care services furnished by civilian providers, physicians, and suppliers to members of the Uniformed Services and to spouses and children of active duty, retired and deceased members. The program is administered by the Department of Defense and funded by the federal government. TRICARE/CHAMPUS pays for, among other items and services, medical devices, and surgeries for its beneficiaries.

b. the Federal Employees Health Benefits Program ("FEHBP") provides healthcare benefits for qualified federal employees and their dependents. It pays for, among other items and services, medical devices and surgeries for its beneficiaries.

In addition, the federal government operates hospitals, including through its Department of Defense and its Department of Veterans Affairs.

B. The False Claims Act

38. The federal False Claims Act, as amended by the Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21 provides, in relevant part:

> **Liability for Certain Acts**. (1) In General – Subject to paragraph (2), any person who – (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; (C) conspires to commit a violation of subparagraph (A), (B)…or (G). . .

> or (G) knowingly makes, uses, or causes to be made or used a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government, is liable to the United States for a civil penalty of not less than [$10,781.00] and not more than [$21,563.00] . . . plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729(a)(1).

39. The FCA provides that any person who knowingly presents or causes another to present a false or fraudulent claim to the Government for payment or approval is liable for a civil penalty for each such claim, plus three times the amount of the damages sustained by the Government. 31 U.S.C. § 3729(a)(1), (2), (7).

40. The FCA empowers private persons who have information regarding a false or fraudulent claim against the Government to bring an action on behalf of the Government and to share in any recovery. 31 U.S.C. § 3730(b)(1). The FCA complaint must be filed under seal without service on any defendant. The complaint remains under seal while the Government conducts an investigation of the allegations in the complaint and determines whether to join the action.

41. The FCA also imposes liability upon persons who knowingly make or cause to be made a false record or statement material to a false claim, as well as persons who conspire to "defraud the Government by getting a false or fraudulent claim allowed or paid." 31 U.S.C. §§ 3729(a)(2) and (a)(3).

42. The FCA, 31 U.S.C. § 3729(b)(1), provides that "(1) the terms 'knowing' and 'knowingly' – (A) mean that a person, with respect to information – (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud."

43. The FCA, 31 U.S.C. § 3729(b)(4), provides that "(4) the term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property."

44. Prior to 2016, the last increases to the penalties for FCA violations occurred on August 30, 1999 and changed the minimum from $5,000.00 to $5,500.00 and the maximum from $10,000.00 to $11,000.00, plus treble damages. 64 Fed. Reg. 47099, 47104 (Aug. 30, 1999). On August 1, 2016, the U.S. Department of Justice published Interim Final Rules, which significantly increased penalties under the False Claims Act for the first time in nearly eighteen years. Now, for violations occurring after November 2, 2015, the new minimum and maximum penalties are $10,781.00 to $21,563.00 plus treble damages. 81 Fed. Reg. 42491, 42494 (Jun. 30, 2016).

C. The Federal Anti-Kickback Statute

45. The federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2)(A) and (B) ("AKS"), prohibits offering to pay or paying any remuneration to any person to induce such person "to purchase . . . any good . . . service, or item for which payment may be made in whole or in part under a federal healthcare program" or "to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program."

46. Pursuant to the AKS, it is unlawful to knowingly offer or pay any remuneration in cash or in kind in exchange for the referral of any product or service (including diagnostic services) for which payment is sought from any federally-funded health care program, including Medicare, Medicaid and TRICARE. The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989); *United States v. Greber*, 760 F.2d 68

(3d Cir. 1985), *cert denied*, 474 U.S. 988 (1985). In order to ensure compliance, every federally-funded health care program requires every provider or supplier to ensure compliance with the provisions of the AKS and other federal laws governing the provision of health care services in the United States.

47. In *McNutt ex rel. U.S. v. Haleyville Medical Supplies, Inc.*, 423 F.3d 1256, 1259 (11th Cir. 2005) (herein "*McNutt*"), neither party disputed that complying with federal healthcare laws, including the AKS, was a condition for payment by CMS. "'The False Claims Act does not create liability merely for a health care provider's disregard of Government regulations or improper internal policies unless, as a result of such acts, the provider knowingly asks the Government to pay amounts it does not owe.' *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002). The violation of the regulations and the corresponding submission of claims for which payment is known by the claimant not to be owed make the claims false under sections 3729(a)(1) and (3)." Overall, *McNutt* demonstrates that violations of federal healthcare laws, including the AKS are considered material and form the basis of a false claim under the False Claims Act.

48. A violation of the AKS constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Any party convicted under the AKS must be excluded from federal health care programs for a term of at least five years. 42 U.S.C. § 1320a-7b. The government may also assess civil money penalties, which could result in treble damages plus $50,000 for each violation of the AKS. 42 U.S.C. § 1320a-7a(a)(7).

49. Importantly, although the AKS does not afford a private right of action, the federal False Claims Act provides a vehicle whereby individuals may bring *qui tam* actions alleging violations of the AKS. *See* 31 U.S.C. §§ 3729 *et seq*.

50. Compliance with the AKS is required for reimbursement of claims from federal

health care programs, and claims made in violation of the law are actionable civilly under the FCA. 42 U.S.C. § 1320a-7b(g) (2010) (stating, in part, that a "claim that includes items or services resulting from a violation of . . . [the Anti-Kickback Statute] constitutes a false or fraudulent claim for purposes of [the FCA]. . . ."); *see also United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 315 (3d Cir. 2011) (stating "[c]ompliance with the AKS is clearly a condition of payment under Parts C and D of Medicare" and holding that "appellants, by alleging that appellees violated the AKS while submitting claims for payment to a federal health insurance program, have stated a plausible claim for relief under the FCA.").

51. The AKS was amended in March 2010 as part of the Patient Protection and Affordable Care Act ("PPACA"), which clarified that all claims resulting from a violation of the AKS are also a violation of the FCA. 42 U.S.C. § 1320a-7(b)(g). The PPACA also amended the Social Security Act's "intent requirement" to make clear that violations of its anti-kickback provisions, like violations of the FCA, may occur even if an individual does "not have actual knowledge" or "specific intent to commit a violation." Public Law No. 111-148, § 6402(h).

52. Proof on an explicit *quid pro quo* is not required to show a violation of the AKS.

D. <u>Obtaining Reimbursement Under the Federal Healthcare Programs.</u>

53. Reimbursement practices under all Government Healthcare Programs closely align with the rules and regulations governing Medicare reimbursement. The most basic requirement for reimbursement eligibility under Medicare, Medicaid, and other Government Healthcare Programs is that the service must be provided and must be reasonable and medically necessary. *See, e.g.*, 42 U.S.C. § 1395y(a)(l)(A); 42 U.S.C. §§ 1396 *et seq.*; 42 C.F.R. §§ 410.50, 411.15, 411.406; *United States v. Rutgard*, 116 F.3d 1270, 1275 (9th Cir. 1997) (TRICARE and Railroad Retirement Health Insurance Program plan follow the same rules and regulations as Medicare,

citing).

54. Medical providers are not permitted to bill the government for medically unnecessary services or procedures performed solely for the profit of the provider. *See generally, supra.* For example, the requisite level of medical necessity may not be met where a particular procedure was deleterious or performed solely for profit. *United States ex rel. Kneepkins v. Gambro Healthcare, Inc.*, 115 F. Supp.2d 35, 41-42 (D. Mass. 2000) (procedures chosen solely for a provider's economic gain are not "medically necessary" as required by claim submission form). Healthcare providers are obligated to assure that services or items ordered or provided to patients will be provided "economically and only when, and to the extent, medically necessary" and "will be of a quality which meets professionally recognized standards of Healthcare," and will be supported by evidence of medical necessity and quality . . .." 42 U.S.C. § 1320c-5(a)(l)-(3). Moreover, coverage for Medicare reimbursement for a particular service may be defined at the national level through a National Coverage Determination (NCD) or pursuant to a Local Coverage Determination (LCD) issued by the Medicare contractor within a particular jurisdiction.

55. Claims for payment of outpatient services from the Government Healthcare Programs must be submitted on Form CMS-1500. The form provides fields prompting the provider submitting the claim to provide appropriate Current Procedural Terminology codes ("CPT Codes") and ICD-9 codes for identifying the particular service for which reimbursement is sought and the basis for its medical necessity.

56. CPT Codes are numbers assigned to every task and service a medical practitioner may provide to a patient, including medical, surgical and diagnostic services. CPT Codes are then used by insurers, including the Government Healthcare Programs, to determine the amount of

reimbursement received. For purposes of this Second Amended Complaint, the relevant CPT Codes for cardiac event monitoring are 93270-93272 and for MCT monitoring are 93228 and 93229.

57. The ICD-9-CM is the official system for assigning codes to describe diagnoses or clinical signs or symptoms associated with the conditions for which healthcare goods and services are rendered in the United States.

58. Reimbursement rules issued by the Government Healthcare Programs identify acceptable ICD-9 code(s) required to demonstrate medical necessity for particular covered goods and services. Eligibility for reimbursement from the Government Healthcare Programs requires consistency between the diagnosis code(s) submitted by the provider and the patient's symptoms and conditions. The ICD-9 codes reported in support of the medical necessity of the associated CPT Codes must reflect conditions and diagnoses fully supported by medical documentation in the patient's record.

59. Each of the Government Healthcare Programs requires every provider who seeks payment from the program to promise and ensure compliance with the provisions of the Anti-Kickback Statute (discussed *infra)* and with other federal laws governing the provision of healthcare services in the United States.

60. For example, physicians, hospitals, and IDTFs enter into Provider Agreements with CMS in order to establish their eligibility to seek reimbursement from the Medicare Program. As part of that agreement, without which hospitals and physicians may not seek reimbursement from Government Healthcare Programs, the provider must sign the following certification:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to [me]. The Medicare laws, regulations, and program instructions

> are available through the [Medicare] contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the [provider's] compliance with all applicable conditions of participation in Medicare.

Form CMS-855A; Form CMS-8551 (effective 2001). In addition, the claims themselves as submitted contain a similar certification. *See, e.g.,*Form CMS-1500.

61. When a provider submits a claim for payment, he or she does so subject to and under the terms of its certification to the United States that the services for which payment is sought were delivered in accordance with federal law.

62. In addition to the general provider enrollment requirements for reimbursement under Government Healthcare Programs, IDTFs such as the one operated by Defendants must comply with a number of specific conditions to maintain federal healthcare program billing privileges, including the requirement to "[o]perate its business in compliance with all applicable Federal and State licensure and regulatory requirements for the health and safety of patients." 42 C.F.R. § 410.33(g).

63. At all times relevant to this Second Amended Complaint, Defendants provided services to patients insured by the Government Healthcare Programs and sought, or caused to be sought, reimbursement for those services.

64. Further, after Defendants perform a test for patients insured by the Government Healthcare Programs, the referring physicians also generally submit claims for reimbursement.

V. FACTUAL BACKGROUND AND ALLEGATIONS

A. Cardiac Monitoring Devices and Reimbursement

65. Cardiac arrhythmia refers to the occurrence of abnormal heart rhythms. Arrhythmias may be accompanied by symptoms (e.g., palpitations, fainting, dizziness, weakness blood clots) or present asymptomatically. Arrhythmias can occur infrequently and unpredictably.

66. Medicare covers costs associated with the diagnosis of cardiac arrhythmias.

67. Some cardiac conditions can be diagnosed upon physical examination or in-office testing. However, if a physician cannot diagnose a patient's condition this way, a variety of ambulatory electrocardiographic (ECG) monitoring devices may be used to assist with diagnosing the patient. The degree and frequency of arrhythmia symptoms dictates the appropriate type and duration of cardiac monitoring.

68. A heart's electrical activity produces currents that radiate through the surrounding tissue to the skin. When electrodes are attached to the skin, they sense those electrical currents and transmit them to an ECG monitor. The currents are then transformed into waveforms that represent the heart's depolarization-repolarization cycle.[2]

69. An ECG is a record of the electrical activity of the heart recorded at the surface of the body. It shows the precise sequence of electrical events occurring in the cardiac cells throughout that process. It allows a provider (*i.e.*, doctor or nurse) or technician to monitor phases of myocardial contraction and to identify rhythm and conduction disturbances. A series of ECGs can be used as a baseline comparison to assess cardiac function.

70. Each phase of cardiac electrical activity produces a specific wave or complex in which the basic ECG waves are labeled alphabetically beginning with the P wave (atrial depolarization).

71. Waveforms produced by the heart's electrical current are recorded on graphed ECG paper by a stylus. ECG paper consists of horizontal and vertical lines forming a grid. A piece of ECG paper is called an ECG strip or tracing.

[2] Myocardial depolarization occurs when a wave of stimulation passes through the heart and stimulates the heart muscle to contract. Repolarization is the return to the resting state and results in relaxation.

72. ECG monitoring - hardwire monitoring or telemetry – generally occurs in the hospital (*i.e.*, intensive care units or emergency rooms), and depends on the patient's condition.

73. With hardwire monitoring, the electrodes are connected directly to the cardiac monitor. Most hardwire monitors are mounted permanently on a shelf or wall near the patient's bed. Some monitors are mounted on an I.V. pole for portability, and some may include a defibrillator. The monitor provides a continuous cardiac rhythm display and transmits the ECG tracing to a console at the nurses' station. Both the monitor and the console have alarms and can print rhythm strips.

74. Telemetry monitoring is generally used in step-down units and medical-surgical units where patients are permitted more activity ("telemetry units").[3] With telemetry monitoring, the patient carries a small, battery-powered transmitter that sends electrical signals to another location, where the signals are displayed on a monitor screen. This type of ECG monitoring frees the patient from cumbersome wires and cables associated with hardwire monitoring.

75. Telemetry monitoring still requires skin electrodes to be placed on the patient's chest. Each electrode is connected by a thin wire to a small transmitter box carried in a pocket or pouch.

1. Types of Remote Cardiac Monitoring Devices.

76. Remote cardiac monitoring technologies allow home ECG monitoring of patients with suspected cardiac arrhythmias or those at risk for developing arrhythmias. Real-time remote cardiac monitoring systems automatically record all of the patient's ECG data and transmit the data set, including arrhythmic event data, to personnel monitoring the data at a facility, clinic or hospital.

[3] Step-down units provide an intermediate level of care between the Intensive Care Units (ICUs) and the general medical-surgical wards. These units are also commonly referred to as intermediate care units and transitional care units.

77. There are three primary types of remote cardiac monitors – Holter monitors, Cardiac Event monitors and Mobile Cardiac Telemetry ("MCT") monitors.

78. These remote cardiac devices and the interpretation of the results are reimbursed at differing rates by Medicare and other Governments Healthcare Programs. The highest reimbursement rate is for MCT.

79. Prior to 2002, two main types of devices - Holter monitors and Cardiac Event monitors – were primarily used for remote cardiac monitoring.

80. Holter monitors record heart rhythms continuously for up to 48 hours. The entire uninterrupted recording is captured on magnetic tape or digital media. After patient recording concludes, the patient must return the device and recorded media to the physician or technician who then is supposed to review the data, interpret a computer-generated report and provide an analysis of the data.

81. Holter monitors are appropriate for patients with demonstrated symptoms occurring with daily frequency.

82. Cardiac Event monitors (or "Event monitors") record heart rhythms for up to 30 days. These devices record heart rhythms upon activation; most Event monitors are designed to be activated by the patient upon experiencing symptoms or automatically triggered by a pre-set computer algorithm intended to detect arrhythmias. Standard "loop" recorders have very limited data storage capacity and are capable of storing only a few minutes of data. Similar to a Holter monitor, the recorded data is captured on an internal media and interpreted by the physician after the patient returns the device or recording.

83. Cardiac Event monitors are generally used for patients with infrequent or irregular presentation of symptoms.

84. Starting in or around 2002, MCT was developed. MCT refers to non-invasive, ambulatory cardiac monitors with extended memory capable of continuous measurement of heart rate and rhythm over several days, with transmission of results to a remote monitoring center. MCT is similar to standard cardiac telemetry used in a hospital setting, but the data is gathered remotely.

85. The MCT monitoring systems were intended to replicate in-hospital monitoring with full disclosure of cardiac data being delivered directly to an IDTF for 24/7 monitoring and/or review. MCT devices record heart rhythms continuously for up to 30 days.

86. The MCT system was created so patients could wear a small sensor and monitor as they go about their daily lives.

2. Differences Between MCT and Event/Holter Monitors

87. The MCT system is fundamentally different from the traditional, less expensive Event monitor systems because MCT supposedly works in "real-time" acquiring and analyzing every heartbeat and transmitting data, including algorithm or patient-initiated events, wirelessly to a designated IDTF.

88. The MCT system differs from Event monitors in that it continuously analyzes all (full-disclosure) of the data and transmits algorithm or patient-activated events and other pertinent data to the diagnostic monitoring center for the creation of the required reports, whereas traditional Event monitors typically send only algorithm-triggered, irregular events or patient-activated events with no other contextual data.

89. For example, Defendant CardioNet claims that CardioNet's MCOT device "proved nearly 3x more effective than LOOP [standard patient-activated external loop] event monitors in diagnosing clinically significant arrythmias" based on a randomized study. *See* Rothman, Steven A., The Diagnosis of Cardiac Arrythmias: A Prospective Multi-Center

Randomized Study Comparing Mobile Cardiac Outpatient Telemetry Versus Standard Loop Event Monitoring, JOURNAL OF CARDIOVASCULAR ELECTROPHYSIOLOGY vol. 18, no. 3 (March 2007).

90. The FDA subjects an event recorder and an arrhythmia detector and alarm to significantly different standard and regulations. In addition, the marketing applications for each device are subject to different levels of FDA review and examination.

91. Pursuant to 21 CFR § 870.1025, FDA defines an arrhythmia detector and alarm as a device intended to "monitor an electrocardiogram and produce a visible or audible signal or alarm when atrial or ventricular arrhythmia, such as premature contraction or ventricular fibrillation, occurs." The detector/alarm is needed to create a more "visible" tracing to assist in reviewing and analyzing a waveform for interpretation.

92. Until 2003, FDA regulated arrhythmia detector and alarm devices as a Class III Preamendment Device for which the submission of a Premarket Approval application is not required. The Federal Food, Drug, and Cosmetic Act defines a Class III medical device as a device that (1) supports or sustains human life or (2) presents a potential unreasonable risk of illness or injury. 21 U.S.C. § 360c(a)(1)(C)(ii).

93. In October 2003, FDA reclassified the arrhythmia detector and alarm as a Class II medical device subject to special controls.[4] In conjunction with this reclassification, FDA issued a guidance document, entitled *"Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm"* ("FDA Guidance"), to mitigate the health risks identified by FDA and ensure the safety

[4] FDA regulates event recorders as a Class II medical devices under 21 CFR § 870.2920, "Telephone Electrocardiograph Transmitter and Receiver." FDA defines a "Telephone Electrocardiograph Transmitter and Receiver" as "a device used to condition an electrocardiograph signal so that it can be transmitted via a telephone line to another location." Though an event recorder meets the general standards applicable to electronic medical devices, it is not subject to any special controls or the FDA Guidance.

and efficacy of these devices.

94. Pursuant to the FDA Guidance, a company intending to market an arrhythmia detector and alarm after October 2003 was required to submit data to FDA demonstrating that its device performs basic cardiac monitoring and ECG functions in accordance with the performance standards contained within ANSI/AAMI EC-13:2002, *"Cardiac Monitors, Heart Rate Meters, and Alarms,"* AAMI EC 11-1991, *"Diagnostic Electrocardiagraphic Devices,"* and AAMI EC 38-1998, *"Ambulatory Electrocardiographs"*. In addition, FDA recommended that a company comply with the requirements outlined in ANSI/AAMI-EC 57:1998, *"Testing and Reporting Performance Results of Cardiac Rhythm and ST Segment Measurement and Algorithms,"* for testing the beat-detection algorithm.

95. Accordingly, as a result of the technological and regulatory differences between the arrhythmia detector and alarm and the event recorder, FDA cleared the devices with very different indications for use.

96. An arrhythmia detector and alarm will be cleared with indications specific to arrhythmia detection. However, an event recorder is intended for use by patients who experience transient symptoms that may suggest cardiac arrhythmia.

97. For example, LifeWatch itself described its product as follows in a federal court complaint:

> LifeWatch's LifeStar Ambulatory Cardiac Telemetry ("ACT") product provides remote cardiac monitoring which rapidly detects, and notifies the patient's doctor concerning, heart rhythm abnormalities. LifeWatch's ACT product and other MCOT devices have saved many lives. By denying coverage for MCOT services, the Blue Cross plans are depriving their subscribers of the **only real time ambulatory event monitors that provide continuous, around-the-clock monitoring services**, and, therefore, are potentially putting many lives at risk.
>
> As occurrences of arrhythmias are detected, transmitted and displayed at the central

> monitoring station, **they are viewed immediately by monitoring staff, who store the data for trend analysis**, and will promptly contact a patient's physician in cases in which the device indicates a potential life-threatening situation or other serious abnormality. This monitoring also allows a report to be prepared for any past 24-48 hour period that the patient is on the system. The LifeStar system has the capability of taking up to 30 days of cardiac data and processing it through specialized scanning software that allows clinicians to review the full amount of the processed data.
>
> LifeWatch has received letters from customers and family members of customers telling how LifeWatch's ACT product and **its real-time monitoring service** saved lives.

Second Amended Complaint, at ¶¶ 3, 47, 54 in *LifeWatch Services, Inc. v. Highmark Inc., et al.*, Case No. 2-13-cv-00598-RDP (N.D. Ala.) (emphasis added).

98. Most MCT devices are worn by patients for a period of time during which the device continuously records the activities of the patient's heart and sends algorithm or patient-initiated events data to an IDTF for a more detailed technician review and analysis of the patient's ECG. The MCT near real-time technology works via embedded cellular modem to a cloud-based or server-based monitoring center for live technician analysis, review, and creation of required reports.

99. Because true MCT offers advanced, full-disclosure ability to view events and near real-time analysis technology, manufacturers claim that it reduces costs and improves the diagnostic quality of ECG monitoring on an outpatient basis.

100. Companies promote and sell MCT services as a unique form of ambulatory cardiac monitoring in comparison to hospital-based telemetry services. In the market, MCT services are commonly referred to as "live telemetry."

101. For example, Defendants have previously advertised their MCOT system using promotional ideas such as "OnStar for the Heart".

3. Reimbursement for MCT

102. All cardiac monitoring services (*i.e.*, diagnosis of cardiac arrhythmias) are

reimbursed at various rates by Medicare and other insurers depending upon the type of device or service. CPT Codes dictate reimbursement levels for the respective services separately performed by physicians versus those monitoring services performed by the IDTF provider.

103. It is far less costly to provide a patient a Holter or Event monitor than to keep them hospitalized for days hoping to capture an ECG event (standard cardiac telemetry used in the hospital setting).

104. Medicare generally covers Holter and Event monitoring for diagnostic purposes, specifically where the treating physician requires the additional information to evaluate a patient's condition because a diagnosis could not be made on physical examination of the patient.

105. Similar to Holter and Event monitoring, MCT monitoring is also covered and payable by Medicare according to specific ICD-10 codes and follows the same evaluation as explained above.

106. Cardiac monitoring services are reimbursed in accordance with separate CPT Codes assigned to the respective services performed by physicians and IDTFs in connection with patient use of the device.

107. Billing for cardiac monitoring services is divided into professional versus technical components. Accordingly, CMS and private payers assign CPT Codes to reimburse treating physicians for their professional services and a separate CPT Codes to reimburse the IDTF for its technical services.

108. For example, treating physicians seek reimbursement for hooking up the Event monitor and for physician review and interpretation, and IDTFs seek reimbursement for the technical component of Event monitoring services, which involves 24/7 monitoring by

technicians, emergent notification, and reporting of patient data and technician observations.

109. By 2009, companies began offering cardiac MCT products and services in addition to the Event monitoring discussed above.

110. Unlike Event monitoring, MCT is not covered by the Government Healthcare Programs under an NCD. Rather, the determination whether to cover mobile telemetry is left to local coverage determinations (LCD) of individual Medicare contractors operating across the country.

111. From 2002 until January 2009, MCT was billed using a miscellaneous CPT Codes (93799-TC and 93799-26), and relied solely on a LCD issued by Highmark Medicare Services, Inc. of Pennsylvania ("Highmark") that CardioNet helped to develop.

112. At the time, Highmark was the Part A and Part B Medicare Administrative Contractor (MAC) for Delaware, Maryland, New Jersey, Pennsylvania and the District of Columbia.

113. The Highmark LCD (M-60D, Real-Time Outpatient Cardiac Monitoring), as of January 13, 2006, defined the service as follows:

> Real-time, outpatient cardiac monitoring is an automatically activated system that requires no patient intervention to either capture or transmit an arrhythmia when it occurs. Upon arrhythmia detection, the device utilizes the standard telephone line or wireless communications and transmits the ECG waveform to the receiving center. The patient's physician is made aware of arrhythmias based on pre-determined notification criteria, tailored to the patient by the physician.
>
> In this system, the patient wears a small telemetry transmitter that sends the ECG to the computer with modem where the real-time analysis occurs. When the ECG violates certain alarm limits, the ECG strip is automatically sent to the receiving center via the computer modem or wireless communication. The receiving center also has the capability to receive and review a patient's ECG strip in real-time, at any time during the episode of monitoring. Qualified technicians perform ECG surveillance 24 hours a day. The patient's physician is notified of ECG abnormalities based on the notification criteria. This rapid arrhythmia recognition and physician notification allows timely intervention. In addition, this system provides an analysis and report of 24 hours of monitoring, similar to Holter studies. Therefore, the concomitant use of cardiac surveillance, Holter monitoring, and /or event monitoring would not be necessary.

114. After Highmark's LCD was issued, several other MACs, at the request of CardioNet, also created billing policies for the professional component of MCT in order for the physicians to receive reimbursement.

115. In October 2008, the American Medical Association (AMA) published it updated CPT Codes.

116. CPT Codes 93228 was assigned to professional remote telemetry services and CPT Codes 93229 was designated for the technical component of remote telemetry services:

- **93228** - Professional - External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real-time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; review and interpretation with report by a physician or other qualified Healthcare professional.

- **93229** – Technical - External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real-time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; technical support for connection and patient instructions for use, attended surveillance, analysis and transmission of daily and emergent data reports as prescribed by a physician or other qualified healthcare professional.[5]

117. Thus, IDTFs, including IDTFs managed by Defendants, seek reimbursement under CPT Codes 93229 for the technical components of telemetry services, including attended surveillance of reported data and transmission of data reports based upon physician-specific criteria and/or frequency.

118. On November 3, 2008, CardioNet announced that CMS had established reimbursement rates that covered MCT services, including CardioNet's MCOT system.

[5] In comparison, physicians use CPT codes 93268 and 93224 to bill for cardiac Holter and Event monitoring services.

119. The reimbursement rates were applicable to the Category I CPT Codes established by the AMA and published in October 2008. The codes and rates were contained in The Medicare Program Final Rule for the calendar year 2009 and became effective on January 1, 2009.

120. The 2009 national reimbursement rate for the technical component related to use of CardioNet's MCOT system (CPT Codes 93229) was "carrier priced", meaning Highmark would continue to be responsible for the reimbursement rate for the new code.

121. Accordingly, starting in January 2009, MCT systems gained momentum with the issuance of the Category I CPT Codes for both the professional and technical component and quickly gained substantial market share and were granted national Medicare coverage. Providing continuous "telemetry" on an outpatient basis was a novel technology.

122. One LCD stated

> As of 01/01/2009, CPT Codes 93228 and 93229 describe wearable mobile cardiovascular telemetry services. Because of this, wearable mobile cardiovascular telemetry services should no longer be reported using 93799 Providers are instructed to bill one (1) unit of procedure code 93228 and/or 93229 per a course of treatment that includes up to 30 consecutive days of cardiac monitoring

123. Many payors, including Blue Cross/Blue Shield, Aetna, HealthNet and CIGNA, had created medical policies to cover MCT prior to the CPT Codes being released. [6]

124. In May 2009, CardioNet announced that Highmark posted a reimbursement rate for CPT Codes 93229 of $1,123.07.[7] The reimbursement of $1,123.07 reflected the same rate announced in November 2008 by Highmark.

125. Because there is no hook-up fee for telemetry the way there is for event

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[6] Even as recently as 2013, "Cigna [did] not cover an external mobile outpatient cardiac telemetry system (CPT codes 93228, 93229) for any indication because it is considered experimental, investigational or unproven." Cigna Medical Coverage Policy (June 2013).

[7] https://www.businesswire.com/portal/site/google/?ndmViewId=news_view&newsId=20090518006529&newsLang=en

monitors, the only CPT Codes for the professional service of the physician is for professional interpretation which was reimbursed at approximately $30 at all times relevant to this Second Amended Complaint. Unlike Event monitoring, there is no “global” reimbursement or CPT Codes for MCT.

126. Upon information and belief, LCDs approving MCT under certain situations were soonissued by Medicare contractors for each of the fifty states and the District of Columbia.

127. For example, Novitas Solutions, Inc. serves as the Medicare Part A and Part B contractor in several jurisdictions nationwide. For each jurisdiction in which it operates, Novitas issued an LCD establishing the narrow criteria under which mobile telemetry services may be covered and the effective date of coverage for such claims. *See, e.g.*, Local Coverage Determination (LCD), Real-Time, Outpatient Cardiac Telemetry (L33075) (Texas) (stating criteria for telemetry coverage in Texas, effective July 11, 2008).

128. A later LCD (L34997) from Novitas defines “Real-Time, Outpatient Cardias Telemetry” as follows:

> Real-time, outpatient cardiac telemetry involves the use of an automatically activated system that requires no patient intervention to either capture or transmit a dysrhythmia when it occurs. The purpose of this service is for real-time, continuous, long term (> 24 hours) cardiac surveillance of patients in order to identify and document a suspected and/or paroxysmal dysrhythmia. The term "real-time” in this Local Coverage Determination (LCD) is defined as the immediate transmission of the patient’s cardiac activity to a receiving center (as defined below) which converts this electronic transmission into a visible image that is constantly and continuously displayed on a monitor in the receiving center so that qualified personnel (as defined below) located in the receiving center can provide immediate and accurate surveillance of the patient’s cardiac activity. The device utilizes technology that allows for the electronic transmission of the electrocardiogram (ECG) waveform in real time to the receiving center. A receiving center is a facility, such as a physician’s office, Independent Diagnostic Testing Facility (IDTF) or other specified station that is equipped and staffed with qualified personnel to assess electrocardiographic data and to initiate appropriate management action. The patient's physician is made aware of dysrhythmias by qualified personnel based on pre-determined notification criteria, tailored to the

> patient by the physician.
>
> In this system, the patient wears a telemetry transmitter that sends the ECG to a computer with modem where the real-time analysis occurs. Qualified personnel constantly provide ECG surveillance while in attendance at the receiving center. All transfer of ongoing telemetry surveillance services to other qualified personnel, including those who may be located at a different receiving center, occur seamlessly, with no gaps in patient surveillance. Qualified personnel at receiving centers thus provide patient telemetry surveillance 24 hours a day, seven days a week. The patient's physician is notified of ECG abnormalities based on the notification criteria. This dysrhythmia recognition and physician notification must allow for immediate medical intervention. An answering service/answering machine does not fulfill this requirement. In addition, this system provides an analysis and report of 24 hours of monitoring, similar to Holter studies. Therefore, the concomitant use of real-time cardiac telemetry, Holter monitoring, and/or event monitoring would be considered not medically necessary.

Available on https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=34997&ContrId=338&ver=10&ContrVer=1&Date=10%2f01%2f2015&DocID=L34997&bc=iAAAAAgAAAAAAA%3d%3d&.

129. The Novitas LCD also sets forth the ICD-9 codes deemed to support a claim that a patient's condition or diagnosis meets the covered indications identified by LCD as medically necessary for telemetry services.

130. Under the current billing model, the referring physician is only compensated for the professional (interpretation) component which requires "24-hour availability, response to emergent events, and interpretation and final reporting" each day for up to 30 days to monitor cardiac events.

131. Providers such as doctors and hospitals seek reimbursement under CPT Codes 93228 for the professional component of MCT, including the rental costs of the device, concurrent computerized real-time data analysis and the physician's review and interpretation component.

132. The technical analysis is (virtually always) the higher reimbursing component for cardiac diagnostics, as it requires 24-hour monitoring. This holds true to Holter monitoring, cardiac event monitoring, echocardiography, nuclear imaging, vascular diagnostics and MCT. The primary

reason for this difference is because the technical component requires significantly greater costs including specialized education and training for staff, labor costs, equipment costs, maintenance costs, supply costs and the time required to generate the final results of the study.

133. Indeed, the Relative Value Units (RVUs)[8] for 93228 (professional) and 93229 (technical) were .74 and 20.25 in 2018 and .74 and 20.31 in 2017, respectively. The high RVU for 93229 drives the rate of reimbursement.

134. In November 2010, CMS established a national price for the CPT Codes for MCT (93229) and all MAC's and localities had pricing assigned to that code for the calendar year 2011. At that point, it was known that Marin County in California was the highest reimbursement in the county for MCT.

B. Defendants' Schemes Are Designed To Reduce And Shorten Costly Technician Time

138. Over time, companies have focused on reducing technician time, which is the major expense line for these businesses by sending less data for review.

139. Defendants have systemically relied on computer algorithms to analyze the data in an attempt to reduce staffing.

140. However, the computer algorithms are not accurate and the IDTFs are producing false, automatically-generated reports without any personal review or visual oversight by a technician.

141. Many MCT systems do not actually provide full-disclosure data for review to the monitoring center; rather, the MCT system typically provides just events and packets of data to complete histograms, and other spurious data points in reports.

[8] RVUs are values assigned by CMS to each CPT/HCPCS code, and represents the cost for providing a service. An RVU is made up of three components: physician work, practice expense, and malpractice overhead. Medicare payments are composed of these values multiplied by factors of conversion and geographical adjustment.

142. In addition, the MCT-applicable coding requires "up to 30-days" of device use. This is another area of concern as the trend in the marketplace is to "churn" the device use.

143. Providers prescribe the technology for 3 to 7 days, and send the device back to be used/billed again. Some IDTF providers provide the practice with in-office inventory to speed up the "churn" and reduce the shipping delays of sending devices back and forth to patients.

144. In addition, Defendants' sales force would educate providers on ways and methods to shorten the time that a MCT device was out with a patient.

C. Defendants Are Improperly Seeking Reimbursement For Monitoring And Analysis At A Higher Rate For Work Performed In Other Locations

145. Defendants are defrauding the Government Healthcare Programs by, among other things, seeking reimbursement for analysis and review performed by technicians located in New Jersey, Minnesota and Pennsylvania, but billed as if the services were performed in California and seeking reimbursement for tests performed by technicians located in India, some of whom are not certified.

146. Defendants bill for IDTF services in jurisdictions outside of where services are provided. Due to higher reimbursement rates outside of a company's current service center location, this has been a common practice with a number of IDTF providers.

147. When billing a federal healthcare program, a provider's expense (overhead cost) is considered when computing the fee.

148. Under Medicare rules, a provider is required to identify the place of service correctly on the claims forms. The provider must do this so the federal program can pay the accurate fee for the services provided. *See, e.g.*, Medicare Claims Manual Transmittal 2679 ("Under Medicare, the correct POS code assignment is also required on the paper claim Form CMS 1500 (or its electronic equivalent).").

149. The reason why the authorities requires this reporting is because different locations may require higher costs to operate. For example, a newer facility may have more overhead costs than an older one, similarly to how a smaller office may require less money to operate than a large one.

150. By including the practice expense in the reimbursement, it is thus ensured that medical services can continue to smoothly run their activities without incurring in potential financial losses.

151. After its original approval in 2002, CardioNet opened its first CardioNet Service Center in Philadelphia, Pennsylvania.

152. CardioNet eventually moved its monitoring center to Conshohocken, Pennsylvania.

153. In or around 2013, CardioNet opened a monitoring center in San Francisco, California.

154. BioTelemetry, and, before it, CardioNet, have billed, and continue to bill, for services claiming that those services were performed at its San Francisco IDTF, but, in reality, the services were performed elsewhere, including in Pennsylvania.

155. The NPI number for Defendants' San Francisco location is 1427320399.

156. For example, BioTelemetry's 2017 10-K stated the following:

Item 2. Properties

As of December 31, 2017, we operate the following leased facilities:

Location	Use	Segment(s)	Square feet	Lease expiry
Malvern, PA	Corporate shared services, operations and monitoring	C, H	61,000	2021
Rosemont, IL	Customer support center, distribution, and administrative	H, T	56,000	2019
Ewing, NJ	Monitoring	H	28,000	2018
Eagan, MN	Monitoring and manufacturing	H, T	24,000	2022
Rochester, NY	Research	R	22,000	2028
San Francisco, CA	Monitoring	H	17,000	2019
Rehovot, Israel	Research, development and manufacturing	H	17,000	2018
Chester, PA	Distribution center	H	16,000	2020
Rockville, MD	Research	R	16,000	2026
Phoenix, AZ	Distribution center	H	11,000	2020
San Diego, CA	Research, development and engineering	T	8,000	2020
Concord, MA	Research and development and distribution	T	7,000	2018
Norfolk, VA	Monitoring	H	5,000	2018

C = Corporate, H = Healthcare, R = Research, T = Technology

157. The company's 2018 10-K stated:

Item 2. Properties

As of December 31, 2018, the following were our material leased facilities:

Location	Use	Segment/ Category	Square feet	Lease expiry
Malvern, PA	Corporate shared services, operations and monitoring	H, C&O	61,000	2021
Rosemont, IL	Corporate shared services, operations, monitoring and distribution	H, C&O	58,000	2024
Ewing, NJ	Monitoring	H	28,000	2019
Rochester, NY	Research services	R	27,000	2028
Eagan, MN	Manufacturing	C&O	24,000	2022
San Francisco, CA	Monitoring, research services	H, R	20,000	2019
Chester, PA	Distribution center	H	16,000	2020
Rockville, MD	Research services	R	13,000	2026
Phoenix, AZ	Distribution center	H	11,000	2020
San Diego, CA	Research, development and engineering	C&O	8,000	2020
Norfolk, VA	Monitoring	H	8,000	2024
Concord, MA	Research and development and distribution	C&O	7,000	2019

H = Healthcare segment, R = Research segment, C&O = Corporate and Other category

158. Thus, BioTelemetry acknowledges that it is providing monitoring services in Malvern, PA; Ewing, NJ; Eagan, MN; San Francisco, CA; and Norfolk, VA. The square footage of the leased

properties should be indicative and relate to the number of services being provided therein.

159. However, the number of services provided by Defendants in San Francisco have risen dramatically since 2012 from 28,059 to 101,037 in 2016. By comparison, services rendered in CardioNet's Pennsylvania site have remained static (36,830 in 2012 to 37,084 in 2016).

160. Similarly, the reimbursement submitted by CardioNet for services provided in California has risen from approximately $63 million in 2012 to more than $378 million in 2016. Charges submitted for services provided in Pennsylvania have decreased from approximately $108 million in 2012 to only $23 million in 2016.

161. On Indeed.com, CardioNet employees recently made the following observations regarding the work they are performing at the company's San Francisco monitoring center:

> The upper management in Pennsylvania could care less about their employees, its basically the concept of how many strips you can do and how fast and accurate you can do them.
>
> * * * * * *
>
> This company could really care less for you as a person except how many strips you can do. **They start you off at 50 strips in 8 hours to 100, 200, and eventually the expectation is 800 strips a day and no mistakes**. The first 2 weeks being at this company are definitely the best, you're able to work in a bi sky rise building in the financial district.

See https://www.indeed.com/cmp/Cardionet/reviews?fcountry=US&floc=San+Francisco%2C+CA&sort=date_asc (last visited on July 23, 2018) (bold and underline added).

162. As Relators believe and allege, these statements indicate that CardioNet employees in San Francisco are reviewing "strips", but do not review patient data. Rather, patient data is already collected and processed in Pennsylvania and/or other sites. Moreover, reviewing 800 "strips" per day is a substantial workload.

163. Similarly, LifeWatch operated an IDTF in Philadelphia, Pennsylvania and billed all of

its "technical" services through Highmark.

164. Upon information and belief, LifeWatch also billed for services using its San Francisco IDTF, but performed the services elsewhere.

165. Additionally, Defendants have used non-U.S. based technical staff to review, analyze and/or interpret data for patients covered by Medicare or other federal programs.

166. CMS interprets the term "Medicare-related work" broadly. Medicare-related work encompasses what "offshore" subcontractors do when they receive, process, transfer, handle, store, or access beneficiary protected health information (PHI) while helping sponsors fulfill their Medicare Part C and Part D contract requirements. For example, the term "Medicare-related work" includes offshore subcontractors that receive radiological images for reading, because beneficiary PHI is included with the radiological image and the diagnosis is transmitted back to the U.S. More examples of Medicare-related work include claims processing, claims data entry services, scanning paper claims to create electronic records, receipt of beneficiary calls, and any situation where the offshore subcontractor may have access to beneficiary PHI.

167. By law, Medicare does not pay for services "which are not provided within the United States," other than in limited circumstances not applicable here. 42 U.S.C.§ 1395y(a)(4). *See also* 42 CFR 411.9(a) ("Medicare does not pay for services furnished outside the United States.").

168. The CMS Medicare Benefit Policy Manual explains that the prohibition on paying for services outside of the United States applies to all services performed by anyone located outside of the United States, and not just services performed on patients who are located outside of the United States. The Medicare Benefit Policy Manual contains the following guidance:

> For example, if a radiologist who practices in India analyzes imaging tests that were performed on a beneficiary in the United States, Medicare would not pay the radiologist or the U.S. facility that performed the imaging test for any of the services that were performed by the radiologist in India.

Medicare Benefit Policy Manual ch 16 § 60.

169. The federal VA program similarly only covers care provided within the United States, other than in limited situations not applicable here. *See* 38 U.S.C. § 1724.

170. A number of Medicaid programs also prohibit payment for work performed outside the United States, including:

- Georgia - Georgia Administrative Code provides, in relevant part, that to receive payments for Medicaid, a provider must "comply with the Rules and the Department's Policies and Procedures, including specifically Part II of the Department's Policies and Procedures for Hospital Services and the Manual." *See* Ga. Comp. R. & Regs. 111-3-6.03(4)(b); Part II of the Department's Policies and Procedures manual for Hospital Services, in turn, states that "Georgia Medicaid does not over services provided in foreign countries."

- Minnesota - Minnesota's Medicaid program also "does not cover out-of-country care. Out-of-country care occurs when an MHCP recipient receives services or supplies outside the United States." *See* Minnesota Provider Manual, Out of State Providers, available at http://www.dhs.state.mn.us/main/idcplg?IdcService=GET_DYNAMIC_CONVERSION&RevisionSelectionMethod=LatestReleased&dDocName=dhs16_146899# (last visited July 23, 2018.

- Texas - Texas only permits reimbursement for out-of-state care in limited circumstances. *See* Tex. Admin. Code. § 352.17 (provider qualifies for reimbursement as an out-of-state provider only if, among other things, the services it provides are performed within the United States).

171. Defendants have failed to disclose that they are using offshore facilities for this work.

172. Specifically, Defendant CardioNet utilizes a company called Techindia Infoway Pvt Ltd. ("Techindia"), which maintains its principal place of business in Chennai, Tamil Nadu, India.

173. CardioNet began utilizing technicians from Techindia in January 2013, and, upon information and belief, continues to use them today, including for patients insured by Government Healthcare Programs.

174. Upon information and belief, Sathya Kumar is the founder and CEO at Techindia, and has met numerous times with CardioNet management.

175. Techindia has been retained by Defendants to perform, among other things, patient monitoring, analysis of reports, and patient verification of insurance.

176. Defendant CardioNet's scheme seeks reimbursement from Medicare and Medicaid for services performed outside the United States. Further, it is illegal for CardioNet to use non-certified technicians to perform the relevant analyses, regardless of where the services are performed.

177. CardioNet has engaged in an intentional scheme to avoid the requirement that it use only certified technicians located in the United States by outsourcing a significant amount of its work to technicians located in India, and then concealing that at least some of those technicians are not certified.

178. CardioNet allows technicians in India to perform a substantial number of tests.

179. In 2013, Techindia monitored approximately 8,500 patients per month for CardioNet. By 2016, that number grew to more than 13,000 per month.

180. Upon information and belief, LifeWatch also utilized technicians from Techindia to monitor patients.

181. CardioNet has received substantial sums of money from Government Healthcare Programs that it was not entitled to receive by fraudulently billing for services performed outside the United States.

182. CardioNet is, and was, well aware that its billing practices were fraudulent, and that it has collected substantial sums from the Government Insurers based on false and fraudulent claims and statements in support of such claims.

D. Defendants Knew Their Conduct Resulted In False Claims

183. In violation of the False Claims Act, 31 U.S.C. § 3729 *et seq.*, and various state false claims acts, Defendants are submitting, or causing to be submitted, claims for payment to federal

government-funded programs including, without limitation, Medicare, Medicaid, the Federal Employees Health Benefits Program, TRICARE/CHAMPUS, and the Veterans Administration arising from the companies' submission of claims to the Government Healthcare Programs for MCT services using codes when those codes were not supported by the underlying data and analysis.

184. Defendants were aware that they were submitting false and fraudulent claims for technical services to the Government Healthcare Programs and/or that they were causing providers to submit false claims for the telemetry professional component.

185. Defendants secured substantial annual revenue as a result of their fraudulent schemes. Indeed, fraudulent practices by cardiac monitoring companies cost the U.S. Government and the *Qui Tam* States and Cities millions of dollars in medically unnecessary services.

186. Indeed, spending for telemetry services rose sharply after 2009, with annual Medicare expenditures for telemetry (CPT Codes 93229) totaling $73 million in 2011—making telemetry the 177th most costly billing code among the over-9500 CPT Codes presently in use at that time. That spending has risen to more than $189 million in CY2016, making telemetry the 80th most costly billing code.

187. None of the Defendants have acted to notify the U.S. Government and the *Qui Tam* States and Cities of these fraudulent schemes and practices or to identify or return any overpayment received from Government Healthcare Programs.

VI. CAUSES OF ACTION

COUNT I
VIOLATIONS OF 31 U.S.C. § 3729(a)(1)(A)
Against All Defendants

188. Relators re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

189. This is a claim for penalties and treble damages under the False Claims Act, 31 U.S.C. § 3729 *et seq*., as amended.

190. During the relevant period, Defendants presented, or caused to be presented, numerous claims for payment to the United States Government and/or the *Qui Tam* States and Cities through the Government Healthcare Programs, including through Medicare and Medicaid, for professional, technical and/or global services related to the use of Defendants' MCT devices and systems.

191. For the reasons alleged herein, many of these claims were knowingly false and fraudulent within the meaning of the FCA. More specifically, Defendants knowingly presented, and/or caused to be presented, to an officer and/or employee of the United States Government and/or the *Qui Tam* States and Cities false and fraudulent claims for payment and approval in violation of 31 U.S.C. § 3729(a)(1)(A).

192. Defendants had actual knowledge of the falsity of these claims, or deliberately ignored or recklessly disregarded their truth or falsity, within the meaning of the FCA.

193. The United States and the *Qui Tam* States and Cities suffered damages as a result of false claims by Defendants and are entitled to recover their losses and otherwise obtain relief available under the FCA.

COUNT II
VIOLATIONS OF 31 U.S.C. § 3729(a)(1)(B)
Against All Defendants

194. Relators re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

195. This is a claim for penalties and treble damages under the False Claims Act, 31 U.S.C. § 3729 et seq., as amended.

196. During the relevant period, Defendants presented numerous records and statements to the United States Government and/or the *Qui Tam* States and Cities through the Government Healthcare Programs, including Medicare and Medicaid for professional, technical and/or global services related to the use of Defendants' MCT devices and systems.

197. For the reasons alleged herein, many of these records and statements were knowingly false and fraudulent within the meaning of the FCA. More specifically, Defendants knowingly made, used and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved by the United States Government and/or the *Qui Tam* States and Cities in violation of 31 U.S.C. § 3729(a)(1)(B).

198. Defendants had actual knowledge of the falsity of these statements, or deliberately ignored or recklessly disregarded their truth or falsity, within the meaning of the FCA.

199. The United States and the *Qui Tam* State and Cities suffered damages as a result of false records and statements by Defendants and are entitled to recover their losses and otherwise obtain relief available under the FCA.

COUNT III
VIOLATIONS OF 31 U.S.C. § 3729(a)(1)(C)
Against All Defendants

200. Relators re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

201. Through the acts described above and otherwise, Defendants entered into a conspiracy or conspiracies to defraud the United States by getting false and fraudulent claims allowed or paid in violation of 31 U.S.C. § 3729(a)(3), and as amended 31 U.S.C. § 3729(a)(1)(C). Defendants also conspired to omit disclosing or to actively conceal facts which, if known, would have reduced Government obligations to it or resulted in repayments from them to Government programs.

202. Defendants, their agents, and their employees have taken substantial steps in furtherance of those conspiracies, *inter alia*, by preparing false records, by submitting claims for reimbursement to the Government for payment or approval, and/or by directing their agents and personnel not to disclose and/or to conceal their fraudulent practices.

203. The United States and the *Qui Tam* States and Cities, unaware of Defendants' conspiracy or the falsity of the records, statements and claims made by Defendants, their agents and employees, and as a result thereof, has paid and continues to pay millions of dollars that it would not otherwise have paid. Furthermore, because of the false records, statements, claims, and omissions by Defendants and their agents and employees, the United States and the *Qui Tam* States and Cities have not recovered federal funds from Defendants that otherwise would have been recovered.

COUNT IV

Arkansas Medicaid Fraud False Claims Act, Ark. Code Ann. § 20-77-901

204. Relators re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

205. This is a claim for treble damages and civil penalties under the Arkansas Medicaid Fraud False Claims Act, Ark. Code Ann. § 20-77-901.

206. By virtue of the illegal acts, as described more fully above, Defendants knowingly presented or caused to be presented to the Arkansas Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement involving professional, technical and/or global services related to the use of Defendants' MCT devices and systems.

207. The Arkansas Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

208. By reason of these payments, the Arkansas Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT V
California False Claims Act, Cal. Gov't Code § 12651 *et seq.*

209. Relators re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

210. This is a claim for treble damages and civil penalties under the California False Claims Act, Cal. Gov't Code § 12651 *et seq.*

211. By virtue of the illegal acts, as described more fully above, Defendants knowingly presented or caused to be presented to the California Medicaid Program (i.e., Medi-Cal) false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement involving professional, technical and/or global services related to the use of Defendants' MCT devices and systems.

212. The California Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

213. By reason of these payments, the California Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT VI
California Insurance Frauds Prevention Act, California Insurance Code § 1871.7

214. Relators re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

215. This is a claim for treble damages and penalties under the California Insurance Frauds Prevention Act, Cal. Ins. Code § 1871.7, as amended (referred to in this Count as "the Act"). The Act provides a civil cause of action against any person who commits the crime of insurance fraud or who offers or pays illegal inducements or kickbacks to secure benefits under a contract of insurance. Cal. Ins. Code §1871.1(e).

216. The Act provides for civil recoveries against persons who violate the provisions of California Penal Code sections 549 or 550, including recovery of up to three times the amount of any fraudulent insurance claims, and fines of between $5,000 and $10,000 for each such claim. Cal. Ins. Code §1871.7(b).

217. Subsection (e) of Cal. Ins. Code §1871.7, the *qui tam* provision of the Act, was patterned after the federal False Claims Act, 31 U.S.C. §§3729 *et seq*., and the California False Claims Act, Cal. Gov't Code §§12650 *et seq*.

218. Subsection (a) of Cal. Ins. Code §1871.7 provides for civil recoveries against persons who "knowingly employ runners, cappers, steerers, or other persons . . . to procure clients or patients to perform or obtain services or benefits under a contract of insurance or that will be the basis for a claim against an insured individual or his or her insurer."

219. Subsection (b) of Cal. Ins. Code § 1871.7 provides a range of penalties for violations of Penal Code sections 549 or 550. Section 549 of the California Penal Code provides criminal penalties for anyone who: solicits, accepts, or refers any business to or from any individual or entity

with the knowledge that, or with reckless disregard for whether, the individual or entity . . . intends to violate Section 550.

220. Section 550 of the Penal Code prohibits the following activities, among others:

> (a) It is unlawful to do any of the following, or to aid, abet, solicit, or conspire with any person to do any of the following:
>
> * * * * * *
>
> (5) Knowingly prepare, make, or subscribe any writing, with the intent to present or use it, or to allow it to be presented, in support of any false or fraudulent claim.
>
> (6) Knowingly make or cause to be made any false or fraudulent claim for payment of a health care benefit.
>
> * * * * * *
>
> (b) It is unlawful to do, or to knowingly assist or conspire with any person to do, any of the following:
>
> (1) Present or cause to be presented any written or oral statement as part of, or in support of or opposition to, a claim for payment or other benefit pursuant to an insurance policy, knowing that the statement contains any false or misleading information concerning any material fact.
>
> (2) Prepare or make any written or oral statement that is intended to be presented to any insurer or any insurance claimant in connection with, or in support of or opposition to, any claim or payment or other benefit pursuant to an insurance policy, knowing that the statement contains any false or misleading information concerning any material fact.
>
> (3) Conceal, or knowingly fail to disclose the occurrence of, an event that affects any person's initial or continued right or entitlement to any insurance benefit or payment, or the amount of any benefit or payment to which the person is entitled.

Cal. Penal Code § 550.

221. By virtue of the acts described in this Complaint, Defendants knowingly presented or caused to be presented, false or fraudulent claims for healthcare benefits, in violation of Penal Code § 550(a).

222. By virtue of the acts described in this Complaint, Defendants also concealed and/or failed to disclose information that would have affected the rights of patients and/or providers to receive reimbursement for mobile cardiac telemetry services, in violation of Penal Code § 550(b).

223. By virtue of these violations of California Penal Code §§ 549 and 550, Defendants violated California Insurance Code § 1871.7(b).

224. Each report that was performed, reviewed and analyzed as part a reimbursable procedure as a result of Defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. Subsequently, each claim for reimbursement for such mobile cardiac telemetry services submitted to a health insurer represents a false or fraudulent claim for payment.

225. Relators cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false or fraudulent claims were presented for payment by hundreds, if not thousands, of separate entities across the State. Relators have no control over or dealings with such entities and has no access to the records in their possession.

226. Private insurers, unaware of Defendants' fraudulent acts and the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continue to pay the claims that would not be paid but for Defendants' unlawful conduct.

227. As a result of Defendants' commission of the insurance fraud described herein, the State of California and its citizens have been damaged in an amount in excess of millions of dollars, exclusive of interest.

228. The California State Government is entitled to receive three times the amount of each claim for compensation submitted by defendants in violation of Cal. Ins. Code §1871.7.

229. Additionally, the California State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

COUNT VII
Colorado Medicaid False Claims Act, Rev. Stat. § 25.5-4-304 *et seq*.

230. Relators re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

231. This is a claim for treble damages and civil penalties under the Colorado Medicaid False Claims Act, Rev. Stat. § 25.5-4-304 *et seq.*

232. By virtue of the illegal acts, as described more fully above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Colorado State Government to approve and pay such false and fraudulent claims involving professional, technical and/or global services related to the use of Defendants' MCT devices and systems.

233. The Colorado State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal inducements and/or business practices.

234. By reason of the Defendant's unlawful acts, the State of Colorado has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

COUNT VIII
Connecticut False Claims Act, Conn. Code § 17b-301b *et seq.*

235. Relators re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

236. This is a claim for treble damages and civil penalties under the Connecticut False Claims Act, Conn. Code § 17b-301b *et seq.*

237. By virtue of the illegal acts, as described more fully above, Defendants knowingly presented or caused to be presented to the Connecticut Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement involving professional, technical and/or global services related to the use of Defendants' MCT devices and systems.

238. The Connecticut Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

239. By reason of these payments, the Connecticut Medicaid Program has been damages, and continues to be damaged in a substantial amount.

COUNT IX
Delaware False Claims Act, Del. Code Ann. tit. 6, § 1201 *et seq*.

240. Relators re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

241. This is a claim for treble damages and civil penalties under the Delaware False Claims Act, Del Code Ann. tit. 6, § 1201 et seq.

242. By virtue of the illegal acts, as described more fully above, Defendants knowingly presented or caused to be presented to the Delaware Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement involving professional, technical and/or global services related to the use of Defendants' MCT devices and systems.

243. The Delaware Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

244. By reason of these payments, the Delaware Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT X
Florida False Claims Act, Fla. Stat. Ann. 5 68.081 *et seq.*

245. Relators re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

246. This is a claim for treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. Ann. § 68.081 et seq.

247. By virtue of the illegal acts, as described more fully above, Defendants knowingly presented or caused to be presented to the Florida Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement involving professional, technical and/or global services related to the use of Defendants' MCT devices and systems.

248. The Florida Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

249. By reason of these payments, the Florida Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XI

Georgia False Claims Act, Ga. Code Ann. § 49-4-168 *et seq.*

250. Relators re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

251. This is a claim for treble damages and civil penalties under the Georgia False Claims Act, Ga. Code Ann. § 49-4-168 et seq.

252. By virtue of the illegal acts, as described more fully above, Defendants knowingly presented or caused to be presented to the Georgia Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement involving professional, technical and/or global services related to the use of Defendants' MCT devices and systems.

253. The Georgia Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

254. By reason of these payments, the Georgia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XII
Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. 17511 *et seq.*

255. Relators re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

256. This is a claim for treble damages and civil penalties under the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. 17511 et seq.

257. By virtue of the illegal acts, as described more fully above, Defendants knowingly presented or caused to be presented to the Illinois Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used a false record or statement involving professional, technical and/or global services related to the use of Defendants' MCT devices and systems.

258. The Illinois Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

259. By reason of these payments, the Illinois Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XIII
Illinois Insurance Claims Frauds Prevention Act,
740 Ill. Comp. Stat. §92

260. Relators re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

261. This is a claim for treble damages and penalties under the Illinois Insurance Claims Fraud Prevention Act, 740 Ill. Comp. Stat. §92/1 *et seq*. ("Illinois Insurance Fraud Act").

262. Subsection 5(a) of the Illinois Insurance Fraud Act provides for a civil cause of action for any person who commits the crime of insurance fraud or who knowingly offers or pays "any remuneration directly or indirectly, in cash or in kind, to induce any person to procure clients or patients to obtain services or benefits under a contract of insurance or that will be the basis for a claim against an insured person or the person's insurer." 740 Ill. Comp. Stat. §92/5(a).

263. Pursuant to 720 Ill. Comp. Stat. §5/46-1 of the Illinois Criminal Code, a person commits the offense of insurance fraud when he or she:

> knowingly obtains, attempts to obtain, or causes to be obtained, by deception, control over the property of an insurance company or self-insured entity by the making of a false claim or by causing a false claim to be made on any policy of insurance issued by an insurance company . . . .

720 Ill. Comp. Stat. §5/46-1(a).

264. Subsection 15(a) of the Illinois Insurance Fraud Act provides for a *qui tam* civil action in order to create incentives for private individuals to disclose and prosecute violations of the statute. Subsection 15(a) provides: "An interested person, including an insurer, may bring a civil action for a violation of this Act for the person and for the State of Illinois. The action shall be brought in the name of the State." 740 Ill. Comp. Stat. §92/15(a).

265. By virtue of the acts described in this Complaint, defendants committed the following acts, or aided and abetted the commission of the following acts, in violation of the Illinois Insurance Fraud Act:

> (a) defendants knowingly offered or paid remuneration directly or indirectly, in cash or in kind, to induce other persons to procure clients or patients to obtain services or benefits under a contract of insurance or that would be the basis for a claim against an insurer, in violation of 740 Ill. Comp. Stat. §92/5(a); and
>
> (b) defendants knowingly obtained, attempted to obtain, and caused to be obtained, by deception, control over the property of an insurance company or self-insured entity by the making of a false claim and by causing a false claim to be made on a policy of insurance issued by an insurance company, in violation of 740 Ill. Comp. Stat.§92/5(b) and 720 Ill. Comp. Stat. §5/46-1(a).

266. Each prescription that was written as a result of defendants' illegal marketing practices, instructions to falsify diagnosis codes to procure reimbursement, and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a health insurer represents a false claim for payment.

267. Relators cannot at this time identify all of the false claims for payment that were caused by defendants' conduct. The false or fraudulent claims were presented by thousands of separate entities across State. Relators have no control over or dealings with such entities and has no access to the records in their possession.

268. Private insurers, unaware of the falsity of the records, statements and claims made or caused to be made by defendants, paid and continue to pay the claims that would not be paid but for defendants' unlawful conduct, and have been damaged thereby.

269. The Illinois State Government is entitled to receive three times the amount of each claim for compensation submitted by defendants in violation of 740 Ill. Comp. Stat. §92. Additionally, the Illinois State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

COUNT XIV
Indiana False Claims and Whistleblower Protection Act, Indiana Code § 5-11-5.5

270. Relators re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

271. This is a claim for treble damages and civil penalties under the Indiana False Claims and Whistleblower Protection Act, Indiana Code § 5-11-5.5.

272. By virtue of the illegal acts, as described more fully above, Defendants knowingly presented or caused to be presented to the Indiana Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement involving professional, technical and/or global services related to the use of Defendants' MCT devices and systems.

273. The Indiana Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

274. By reason of these payments, the Indiana Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XV
Iowa False Claims Act, Iowa Code § 685.3(2)(a)

275. Relators re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

276. This is a claim for treble damages and civil penalties under the Iowa False Claims Act, Iowa Code § 685.3(2)(a).

277. By virtue of the illegal acts, as described more fully above, Defendants knowingly presented or caused to be presented to the Iowa Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be

made or used, a false record or statement involving professional, technical and/or global services related to the use of Defendants' MCT devices and systems.

278. The State of Iowa, or its political subdivisions, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid for claims that otherwise would not have been allowed.

279. By reason of these payments, the Iowa Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XVI
Louisiana Medical Assistance Programs Integrity Law,
La. Rev. Stat. Ann. § 46:439.1 *et seq.*

280. Relators re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

281. This is a claim for treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:439.1 *et seq*.

282. By virtue of the illegal acts, as described more fully above, Defendants knowingly presented or caused to be presented to the Louisiana Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement involving professional, technical and/or global services related to the use of Defendants' MCT devices and systems.

283. The Louisiana Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

284. By reason of these payments, the Louisiana Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XVII
Maryland False Claims Act, Md. Code Ann. §2-601 *et seq.*

285. Relators re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

286. This is a claim for treble damages and civil penalties under the Maryland False Health Claims Act of 2010, Md. Code Ann. § 2-601 *et seq*.

287. By virtue of the illegal acts, as described more fully above, Defendants knowingly presented or caused to be presented to the Maryland Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement involving professional, technical and/or global services related to the use of Defendants' MCT devices and systems.

288. The Maryland Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

289. By reason of these payments, the Maryland Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XVIII
Massachusetts False Claims Act, Mass. Ann. Laws ch. 12, § 5(A) *et seq.*

290. Relators re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

291. This is a claim for treble damages and civil penalties under the Massachusetts False Claims Act. Mass. Ann. Laws ch. 12, § 5(A) *et seq.*

292. By virtue of the schemes and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Massachusetts Medicaid Program false or

fraudulent claims for the improper payment or approval of prescriptions for the Product described above and used false or fraudulent records to accomplish this purpose.

293. The Massachusetts Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

294. By reason of these payments, the Massachusetts Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XIX
Michigan Medicaid False Claims Act, MCLA §§ 400.601

295. Relators re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

296. This is a claim for treble damages and civil penalties under the Michigan Medicaid False Claims Act, MCLA, §§ 400.601.

297. By virtue of the illegal acts, as described more fully above, Defendants knowingly presented or caused to be presented to the Michigan Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement involving professional, technical and/or global services related to the use of Defendants' MCT devices and systems.

298. The Michigan Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

299. By reason of these payments, the Michigan Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XX
Nevada False Claims Act, Nev. Rev. Stat. § 357.010 *et seq.*

300. Relators re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

301. This is a claim for treble damages and civil penalties under the Nevada False Claims Act, Nev. Rev. Stat. § 357.010 *et seq*.

302. By virtue of the illegal acts, as described more fully above, Defendants knowingly presented or caused to be presented to the Nevada Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement involving professional, technical and/or global services related to the use of Defendants' MCT devices and systems.

303. The Nevada Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

304. By reason of these payments, the Nevada Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXI

New Jersey False Claims Act, N.J. Stat. §§ 2A:32C-1 *et seq.*

305. Relators re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

306. This is a claim for treble damages and civil penalties under the New Jersey False Claims Act, N.J. Stat. §§ 2A:32C-1 *et seq*.

307. By virtue of the illegal acts, as described more fully above, Defendants knowingly presented or caused to be presented to the New Jersey Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be

made or used, a false record or statement involving professional, technical and/or global services related to the use of Defendants' MCT devices and systems.

308. The New Jersey Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

309. By reason of these payments, the New Jersey Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXII
New York False Claims Act, N.Y. State Fin. Law § 187

310. Relators re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

311. This is a claim for treble damages and civil penalties under the New York False Claims Act, N.Y. State Fin. Law § 187.

312. By virtue of the illegal acts, as described more fully above, Defendants knowingly presented or caused to be presented to the New York Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used a false record or statement involving professional, technical and/or global services related to the use of Defendants' MCT devices and systems.

313. The New York Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

314. By reason of these payments, the New York Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXIII
North Carolina False Claims Act, N.C.G.S §§1-605 *et seq.*

315. Relators re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

316. This is a claim for treble damages and civil penalties under the North Carolina False Claims Act, N.C.G.S §§1-605 *et seq.*

317. By virtue of the illegal acts, as described more fully above, Defendants knowingly presented or caused to be presented to the North Carolina Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used a false record or statement involving professional, technical and/or global services related to the use of Defendants' MCT devices and systems.

318. The North Carolina Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

319. By reason of these payments, the North Carolina Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXIV
Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63 § 5053

320. Relators re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

321. This is a claim for treble damages and civil penalties under the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63 § 5053.

322. By virtue of the illegal acts, as described more fully above, Defendants knowingly presented or caused to be presented to the Oklahoma Medicaid Program false or fraudulent claims for

payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used a false record or statement involving professional, technical and/or global services related to the use of Defendants' MCT devices and systems.

323. The Oklahoma Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

324. By reason of these payments, the Oklahoma Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXV
Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1 *et seq.*

325. Relators re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

326. This is a claim for treble damages and civil penalties under the Rhode Island False Claims Act. R.I. Gen. Laws § 9-1.1-1 *et seq.*

327. By virtue of the illegal acts, as described more fully above, Defendants knowingly presented or caused to be presented to the Rhoda Island Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used a false record or statement involving professional, technical and/or global services related to the use of Defendants' MCT devices and systems.

328. The Rhode Island Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

329. By reason of these payments, the Rhode Island Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXVI
Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.* and Tennessee False Claims Act, Tenn. Code Ann. § 4-18-101 *et seq.*

330. Relators re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

331. This is a claim for treble damages and civil penalties under the Tennessee Medicaid False Claims Act, and the Tennessee False Claims Act, Tenn. Code Ann. § 71-5-181 et seq.; Tenn. Code Ann. § 4-1 8-101 et seq.

332. By virtue of the illegal acts, as described more fully above, Defendants knowingly presented or caused to be presented to the Tennessee Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement involving professional, technical and/or global services related to the use of Defendants' MCT devices and systems.

333. The Tennessee Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

334. By reason of these payments, the Tennessee Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXVII
Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. § 36.001 *et seq.*

335. Relators re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

336. This is a claim for treble damages and civil penalties under the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. § 36.001 et seq.

337. By virtue of the illegal acts, as described more fully above, Defendants knowingly presented or caused to be presented to the Texas Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement involving professional, technical and/or global services related to the use of Defendants' MCT devices and systems.

338. The Texas Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

339. By reason of these payments, the Texas Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXIII
Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 *et seq.*

366. Relators re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

367. This is a claim for treble damages and civil penalties under the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-21 6.1 *et seq.*

368. By virtue of the illegal acts, described more fully above, Defendants knowingly presented or caused to be presented to the Virginia Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement involving professional, technical and/or global services related to the use of Defendants' MCT devices and systems.

369. The Virginia Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

370. By reason of these payments, the Virginia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXIX
Washington Medicaid False Claims Act, RCW 74.66.020 *et seq*.

371. Relators re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

372. This is a claim for treble damages and civil penalties under the Washington Medicaid Fraud False Claims Act, RCW 74.66.020.

373. By virtue of the illegal acts, as described more fully above, Defendants knowingly presented or caused to be presented to the Washington Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement involving professional, technical and/or global services related to the use of Defendants' MCT devices and systems.

374. The Washington Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

375. By reason of these payments, the Washington Medicaid Program has been damaged, and continues to be damaged in a substantial amount**.**

COUNT XXX
Wisconsin False Claims for Medical Assistance Act,
Wis. Stat. §§ 20.931 *et seq.*

376. Relators re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

377. This is a claim for treble damages and civil penalties under the Wisconsin False Claims for Medical Assistance Act, Wis. Stat. §§ 20.931 *et seq.*

378. By virtue of the illegal acts, as described more fully above, Defendants knowingly presented or caused to be presented to the Wisconsin Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement involving professional, technical and/or global services related to the use of Defendants' MCT devices and systems.

379. The Wisconsin Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

380. By reason of these payments, the Wisconsin Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXXI
Chicago False Claims Act, § 1-22-010 *et seq.*

381. Relators re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

382. This is a claim for treble damages and civil penalties under the Chicago False Claims Act, § 1-22-010 *et seq.*

383. By virtue of the illegal acts, as described more fully above, Defendant knowingly presented or caused to be presented to the City of Chicago Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

384. The City of Chicago Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

385. By reason of these payments, the City of Chicago Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

Upon information and belief, Defendant is a "city contractor" as that phrase is defined in the Chicago Municipal Code, § 1-22-030

COUNT XXXII
District of Columbia False Claims Act, D.C. Code § 2-308.14 *et seq.*

386. Relators re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

387. This is a claim for treble damages and civil penalties under the District of Columbia False Claims Act, D.C. Code 5 2-308.14 *et seq.*

388. By virtue of the illegal acts, as described more fully above, Defendants knowingly presented or caused to be presented to the District of Columbia Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement involving professional, technical and/or global services related to the use of Defendants' MCT devices and systems.

389. The District of Columbia Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

390. By reason of these payments, the District of Columbia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXXIII
New York City False Claims Act
New York City Adm. Code, § 7-801 *et seq.*

391. Relators re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

392. This is a claim for treble damages and civil penalties under the New York False Claims Act, New York Adm. Code, § 7-801.

393. By virtue of the illegal acts, as described more fully above, Defendants knowingly caused to be presented to New York City false or fraudulent claims for the improper payment or approval of reimbursement for the devices identified above and used false or fraudulent records to accomplish this purpose.

394. The New York City Health and Hospitals Corporation, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

395. By reason of these payments, the New York City Health and Hospitals Corporation has been damaged, and continues to be damaged in a significant amount.

COUNT XXXIV
Hawaii False Claims Act, Haw. Rev. Stat. § 661-22 *et seq.*

396. Relators re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

397. This is a claim for treble damages and civil penalties under the Hawaii False Claims Act, Haw. Rev. Stat. § 661-22 *et seq.*

398. By virtue of the illegal acts, as described more fully above, Defendant knowingly presented or caused to be presented to the Hawaii Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

399. The Hawaii Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.
By reason of these payments, the Hawaii Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXXV
Minnesota False Claims Act, § 15C.01 *et seq.*

400. Relators re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

401. This is a claim for treble damages and civil penalties under the Minnesota False Claims Act, § 15C.01 *et seq.*

402. By virtue of the illegal acts, as described more fully above, Defendant knowingly presented or caused to be presented to the Minnesota Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

403. The Minnesota Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

404. By reason of these payments, the Minnesota Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXXVI
Montana False Claims Act, Mont. Code Ann. § 17-8-401

405. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

406. This is a claim for treble damages and civil penalties under the Montana False Claims Act, Mont. Code Ann. § 17-8-401.

407. By virtue of the illegal acts, as described more fully above, Defendant knowingly presented or caused to be presented to the Montana Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

408. The Montana Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed. By reason of these payments, the Montana Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXXVII
New Mexico Medicaid False Claims Act, N.M. Stat. § 27-14-1 *et seq.*
New Mexico Fraud Against Taxpayers Act, N.M. Stat. § 44-9-1 *et seq.*

409. Relators re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

410. This is a claim for treble damages and civil penalties under the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. 1978, § 27-14-1 *et seq.*

411. By virtue of the illegal acts, as described more fully above, Defendant knowingly presented or caused to be presented to the New Mexico Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used a false record or statement.

412. The New Mexico Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed. By reason of these payments, the New Mexico Medicaid Program has been damaged, and continues to be damaged in a substantial amount

VII. DAMAGES

413. Relators repeat and re-allege each allegation in each of the preceding paragraphs as if fully set forth herein.

414. The FCA imposes liability on any person who

> knowingly presents or causes to be presented a false or fraudulent claim for payment or approval; knowingly makes, uses or causes to be made or used, a false record or

> statement material to a false or fraudulent claim; conspires to commit a violation of the False Claims Act… or knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.

31 U.S.C. § 3729(a). Prior to 2016, the last increases to the penalties for False Claims Act violations occurred on August 30, 1999 and changed the minimum from $5,000.00 to $5,500.00 and the maximum from $10,000.00 to $11,000.00, plus treble damages. 64 Fed. Reg. 47099, 47104 (Aug. 30, 1999). On August 1, 2016, the U.S. Department of Justice published Interim Final Rules, which significantly increased penalties under the False Claims Act for the first time in nearly eighteen years. Now, for violations occurring after November 2, 2015, the new minimum and maximum penalties are $10,781.00 to $21,563.00 plus treble damages. 81 Fed. Reg. 42491, 42494 (Jun. 30, 2016).

PRAYER FOR RELIEF

WHEREFORE, Relators pray for judgment as follows:

A. That Defendants be ordered to cease and desist from violating 31 U.S.C. §3729 *et seq*.; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; and the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812;

B. That this Court enter judgment against Defendants in an amount equal to treble (three times) the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty of not less than $5,500.00 and not more than $11,000.00 for each violation of 31 U.S.C. § 3729 prior to November 2, 2015;

C. That this Court enter judgment against Defendants in an amount equal to treble (three times) the amount of damages the United States has sustained because of defendants' actions, plus a civil penalty of not less than $10,781.00 and not more than $21,563.00 for each violation of 31 U.S.C. § 3729 after November 2, 2015, pursuant to 81 Fed. Reg. 42491, 42494 (Jun. 30, 2016);

D. That Relators be awarded the maximum amount allowed pursuant to § 3730(d) of the False Claims Act;

E. The Relators and the U.S. Government recover the maximum amount under the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a;

F. The Relators and the U.S. Government recover the maximum amount under the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812;

G. That Relators and the U.S. Government be awarded all costs of this action, including attorneys' fees and expenses; and

H. For such other and further relief as this Court may deem proper.

Respectfully submitted,

Dated: March 20, 2019

/s/ Brian J. McCormick, Jr.
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